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Joseph Weathered

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S)	:	Mark B. Knudson, et al.
SERIAL NO.	:	10/682,067
FILED	:	October 9, 2003
FOR	:	Method and Apparatus for Performing Coronary Artery Bypass Surgery
GROUP ART UNIT	:	3738
EXAMINER	:	David J. Isabella

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF SUBSTITUTE BRIEF ON APPEAL

S I R:

In response to the Notification of Non-Compliant Appeal Brief, mailed 12 February 2008 in the above-identified application, enclosed herewith is a substitute Appeal Brief.

The enclosed Brief on Appeal is identical to that filed on 25 January 2008, except that the enclosed Brief additionally includes a description of the status of canceled claims 1-15, 26-30, 32, 42, and 52 in the Status of Claims section.

The Appeal Brief Fee of Two-Hundred-and-Fifty Dollars ($250.00) has already been submitted.

Please charge any additional fees due in connection with this communication to Deposit Account No. 04-0838. A copy of this Transmittal is enclosed for deposit account charging purposes.

Respectfully submitted,

COLEMAN SUDOL SAPONE, P.C.

Dated: 14 February 2008

By: _____
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CERTIFICATE OF MAILING

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BRIEF ON APPEAL

1. REAL PARTY IN INTEREST

The real party of interest in the present application is Wilk Patent Development Corporation, a corporation formed under the laws of the State of New York, having a primary business address at 475 East 72nd Street, Suite 1L, New York, New York 10021. Wilk Patent Development Corporation owns the entire right, interest, and title to the present application by virtue of an Asset Purchase Agreement submitted in redacted photocopy in this case heretofore. The same redacted copy has been recorded in the

assignment records of the Patent and Trademark Office at Reel No. 019457, Frames 0815 et seq.

2. RELATED APPEALS AND INTERFERENCES

Wilk Patent Development Corporation and the undersigned attorney for Wilk Patent Development Corporation are not currently aware of any cases currently on appeal before the Board which may have a bearing on the Board's decision in the instant Appeal. However, the Asset Purchase Agreement referred to above involved a large number of related cases, which the undersigned has not yet had an opportunity to process. It may be that one or more of those cases are currently on appeal and have issues pertinent to the present appeal. If any such cases are discovered, the undersigned shall report them to the Board.

3. STATUS OF CLAIMS

Claims 16-25, 31, 33-41, 43-51, and 53-64 are pending in the application. Claims 1-15, 26-30, 32, 42, and 52 are canceled. Claims 16, 18-22, 24, 31, 33-41, 43-51, and 53-64 are subject to the instant appeal. Claims 17, 23 and 25 have been withdrawn from consideration. Claims 16, 22, and 24 are the only independent claims on appeal. All of the appealed claims stand rejected under 35 U.S.C. § 102(b) as being anticipated by prior art or, in the alternative, as being obvious over prior art (U.S. Patent No. 4,787,899 to Lazarus, U.S. Patent No. 4,604,762 to Robinson, U.S. Patent No. 5,123,917 to Lee, U.S. Patent No. 2,127,903 to Bowen).

The appealed claims are set forth in Appendix A.

4. STATUS OF AMENDMENTS

All Amendments have been entered.

5. SUMMARY OF THE CLAIMED SUBJECT MATTER

As set forth in independent claim 16, a bypass conduit for use in a wall of a heart comprises a hollow conduit having an interior and an exterior and adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart (Paragraphs 0099, 0101 of the

published application), wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place. The conduit is sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole. (Paragraphs 0051, 0099, 0115, 0130 of the published application)

As recited in independent claim 22, a bypass conduit for use in a wall of a heart comprises a hollow conduit having a plurality of circular rings, an interior, and an exterior and adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart, wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place. The conduit is sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole. (Paragraphs 0051, 0099, 0115, 0130 of the published application.)

Accordingly to independent claim 24, a conduit for placing a coronary vessel of a patient's heart in communication with a heart chamber comprises a tubular element configured to be positioned in the wall of a patient's heart, the tubular element including first and second ends and a bore defining a blood flow path. A vessel supporting mechanism is carried by the tubular element, the vessel supporting mechanism being positioned on the conduit so as to contact and support the wall of a coronary vessel when the conduit is positioned in the heart wall. The conduit is sufficiently rigid such that the blood flow path remains open during both systole and diastole. (Paragraphs 0051, 0099, 0115, 0130 of the published application.)

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 16, 18-22, 24, 31, 33-41, 43-51, and 53-64 are properly rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,787,899 to Lazarus.

Whether claims 16, 18-22, 24, 31, 33-41, 43-51, and 53-64 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,787,899 to Lazarus.

Whether claims 16, 18-22, 24, 31, 33-41, 43-51, and 53-64 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,787,899 to Lazarus in view of either of U.S. Patent No. 4,604,762 to Robinson or U.S. Patent No. 5,123,917 to Lee.

Whether claims 37, 46 and 63 are properly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,787,899 to Lazarus in view of either of U.S. Patent No. 2,127,903 to Bowen.

8. ARGUMENT

A. Rejection of Independent Claims 16, 22, and 24 Under 35 U.S.C. §102(b) and §103(a)

Claims 16, 22 and 24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,787,899 to Lazarus.

Claims 16, 22 and 24 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,787,899 to Lazarus.

Claims 16, 22 and 24 additionally stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,787,899 to Lazarus in view of either of U.S. Patent No. 4,604,762 to Robinson or U.S. Patent No. 5,123,917 to Lee.

Appellants traverse the Examiner's rejections of claims 16, 22 and 24 under 35 U.S.C. § 102(b) and § 103(a) maintain that claims 16, 22 and 24 distinguish the invention over Lazarus, as well as over Lazarus in view of Robinson or Lee.

Appellants direct their arguments here to claim 16. Claim 16 is representative of claims 22 and 24. Claims 22 and 24 distinguish over the cited art for the same reasons as claim 16.

As set forth in independent claim 16, a bypass conduit for use in a wall of a heart comprises a hollow conduit having an interior and an exterior and adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart, wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place. The conduit is

sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole.

Lazarus does not disclose or suggest the invention of claim 16. Claim 16 recites a conduit "adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart " and "is sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole."

Lazarus is directed to an intraluminal grafting system particularly including a graft prosthesis for placement within a corporeal lumen, such as a blood vessel or artery. Manifestly, the tubular graft of Lazarus is not adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart. A graft pursuant to the teachings of Lazarus will not have suitable dimensions for placement in the heart wall between a coronary vessel and a chamber in the heart. In particular, the graft will not have a length and a diameter suitable for myocardial placement. Moreover, a graft pursuant to the teachings of Lazarus will not have sufficient rigidity to withstand the compressive stresses in the heart wall during systolic contraction. The principal forces experienced by an intravascular graft are ***tensile*** forces tending to ***expand*** the graft, not ***compressive*** forces which tend to contract and crush the graft. This is evident from the disclosure of Lazarus:

> After emplacement, it can be seen that the ***pressure of the lumen fluid***, for example blood, ***forces the graft 12 against the lumen interior surface*** 112, to hold the graft 12 in place. The bifolds 50 of the graft 12 permit ***deformation*** of the graft 12 to ***conform*** to the interior surface 112 of the lumen, Further, the bifolds 50 act somewhat as a mechanical labyrinth seal to reduce leakage between the interior surface of the lumen 112 and the exterior surface 84 of the graft 12. Similarly, the ***internal pressure of the fluid within the lumen*** 90 holds the graft 12 in place and prevents leakage at the distal end 88 of the graft 12. That is, again the bifolds 50 of the graft 12 act as a mechanical labyrinth seal to reduce leakage between the interior surface of the lumen 112 and the exterior surface 84 of the graft 12. (Paragraph bridging columns 6 and 7.)(Emphasis added.)

Accordingly, the engineering considerations in designing the graft of Lazarus stand in opposition to the engineering constraints of appellants' intra-myocardial conduit. The graft of

Lazarus would have neither the dimensions nor the rigidity suitable for intra-myocardial placement.

One of ordinary skill in the art proceeding from the teachings of Lazarus would have no reason or motivation to provide a conduit "adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart" and "sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole." To design a conduit for intravascular use but having sufficient strength or rigidity to withstand the high compressive forces of the cardiac cycle would amount to engineering overkill. It would not make sense in view of the disclosure of Lazarus.

The Examiner maintains that the language "for use in a wall of a heart" and "adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart" is directed to a method for using the bypass conduit and does not in itself serve to further limit the structure of the conduit. As implicit in the observations made above, appellants disagree. The language "for use in a wall of a heart" and "adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart" places structural limitations on the dimensions and compressive strength of the bypass conduit.

Appellants also contravene the Examiner's assertion that the "properties that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart." The grafts of Lazarus are not at all likely to fit in the myocardium between a ventricle and a coronary artery. Surely, the dimensions of a Lazarus graft will usually be so different from the relevant cardiac dimensions that the Lazarus graft will be unusable for cardiac implantation. There is no inherency.

The Examiner states that the "properties that are inherent in the conduit of Lazarus would equally allow for its placement in the heart wall between a coronary vessel and a chamber in the heart." As discussed above, the conduit of Lazarus is designed from operation under expansive stresses, not compressive stresses. The inherent properties of the Lazarus conduit are not at all suitable for implantation into the heart wall.

The Examiner remarks that "[t]here is no disclosure in Lazarus which would preclude the use of the vessel in the wall of the heart, and therefore, the vessel of Lazarus is capable of performing the recited function." Appellants disagree with the Examiner's reasoning and conclusion. The teachings of Lazarus are directed solely to an intravascular conduit or vessel. As pointed out above, the physical requirements (dimensions and rigidity) of vascular grafts are much different from those of cardiac implants. The vessel of Lazarus would not be capable of performing appellants' recited function.

The Examiner's citation of rejection of Robinson and Lee is not sufficient to render appellants' claim 16 unpatentable. Like Lazarus, both of those references are directed to intravascular grafts or conduits. The dimensions of such grafts are not suitable for intra-myocardial use. Moreover, as discussed above, intravascular stents or conduits are designed to function under substantial tensile forces and are not designed to withstand significant compressive forces. In contrast, appellants' conduit is "adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart" and is "sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole." The engineering constraints or specifications of intra-myocardial conduits and intravascular conduits are inherently different.

9. CONCLUSION

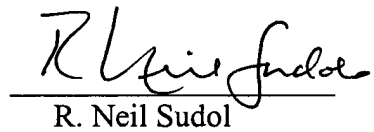
In summary, Lazarus does not anticipate or render obvious appellants' independent claims 16, 22 and 24. Lazarus in combination with Robinson or Lee likewise does not render obvious appellants' independent claims 16, 22 and 24.

For the foregoing reasons, the rejections of claims 16, 18-22, 24, 31, 33-41, 43-51, and 53-64 under 35 U.S.C. §§ 102(b) and 103(a) are deemed to be improper. Appellants therefore request that the Examiner be reversed and the application remanded for proceedings towards issuance.

Respectfully submitted,

COLEMAN SUDOL SAPONE, P.C.

Dated: 14 February 2008

By: 

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APPENDIX A

16. A bypass conduit for use in a wall of a heart, comprising:

a hollow conduit having an interior and an exterior and adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart, wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place,

wherein the conduit is sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole.

18. The device of claim 16, wherein the chamber is the left ventricle.

19. The device of claim 16, wherein the attachment mechanism is selected from the group consisting of hooks, barbs, flanges, collars, suture holes, and expandable legs.

20. The device of claim 16, wherein the attachment mechanism is adapted to anchor the conduit in the heart wall.

21. The device of claim 16, wherein the attachment mechanism is adapted to anchor the conduit in the coronary vessel.

22. A bypass conduit for use in a wall of a heart, comprising:

a hollow conduit having a plurality of circular rings, an interior, and an exterior and adapted to be positioned in the heart wall between a coronary vessel and a chamber in the heart, wherein the conduit has an attachment mechanism on at least one end adapted to anchor the conduit in place,,

wherein the conduit is sufficiently rigid such that a pathway between the coronary vessel and the chamber defined by the conduit remains open during both systole and diastole.

24. A conduit for placing a coronary vessel of a patient's heart in communication with a heart chamber, the conduit comprising:

a tubular element configured to be positioned in the wall of a patient's heart, the tubular element including first and second ends and a bore defining a blood flow path; and

a vessel supporting mechanism carried by the tubular element, the vessel supporting mechanism being positioned on the conduit so as to contact and support the wall of a coronary vessel when the conduit is positioned in the heart wall,

wherein the conduit is sufficiently rigid such that the blood flow path remains open during both systole and diastole.

31. The device of claim 16, wherein the coronary vessel is a coronary artery.

33. The device of claim 16, wherein the conduit includes a plurality of rings.

34. The device of claim 16, wherein the conduit includes a membrane.

35. The device of claim 34, wherein the conduit includes a plurality of rings and the membrane surrounds the plurality of rings.

36. The device of claim 16, wherein the conduit defines a lumen and the conduit is configured to prevent the lumen from collapsing by reason of contraction of the wall surrounding the conduit.

37. The device of claim 16, wherein the conduit defines a channel that includes an angled or curved portion.

38. The device of claim 16, wherein the conduit is configured to expand and contract.

39. The device of claim 16, wherein the attachment mechanism is configured to contact an inner surface of the chamber.

40. The bypass conduit of claim 22, wherein the coronary vessel is a coronary artery.

41. The bypass conduit of claim 22, wherein the chamber is a left ventricle.

43. The bypass conduit of claim 22, wherein the conduit includes a membrane.

44. The bypass conduit of claim 43, wherein the membrane surrounds the plurality of circular rings.

45. The bypass conduit of claim 22, wherein the conduit defines a lumen and the conduit is configured to prevent the lumen from collapsing by reason of contraction of the wall surrounding the conduit.

46. The bypass conduit of claim 22, wherein the conduit defines a channel that includes an angled or curved portion.

47. The bypass conduit of claim 22, wherein the conduit is configured to expand and contract.

48. The bypass conduit of claim 22, wherein the attachment mechanism is configured to contact an inner surface of the chamber.

49. The bypass conduit of claim 22, wherein the attachment mechanism is selected from the group consisting of hooks, barbs, flanges, collars, suture holes, and expandable legs.

50. The bypass conduit of claim 22, wherein the attachment mechanism is adapted to anchor the conduit in the heart wall.

51. The conduit of claim 24, wherein the coronary vessel is a coronary artery.

53. The conduit of claim 24, wherein the conduit includes a plurality of rings.

54. The conduit of claim 24, wherein the conduit includes a membrane.

55. The conduit of claim 54, wherein the conduit includes a plurality of rings and the membrane surrounds the plurality of rings.

56. The conduit of claim 24, wherein the conduit is configured to prevent the blood flow path from collapsing by reason of contraction of the wall surrounding the conduit.

57. The conduit of claim 24, wherein the conduit is configured to expand and contract.

58. The conduit of claim 24, further comprising an attachment mechanism on at least one end adapted to anchor the conduit in place.

59. The conduit of claim 58, wherein the attachment mechanism is configured to contact an inner surface of the chamber.

60. The conduit of claim 58, wherein the attachment mechanism is selected from the group consisting of hooks, barbs, flanges, collars, suture holes, and expandable legs.

61. The conduit of claim 58, wherein the attachment mechanism is adapted to anchor the conduit in the heart wall.

62. The conduit of claim 24, wherein the vessel supporting mechanism is substantially axially aligned with the coronary vessel.

63. The conduit of claim 24, wherein the vessel supporting mechanism extends substantially perpendicularly to the tubular element.

64. The conduit of claim 24, wherein the vessel supporting mechanism is configured to be in blood flow communication with the coronary vessel.

APPENDIX B: EVIDENCE APPENDIX

No evidence was submitted in the application pursuant to 37 C.F.R. Sections 1.130, 1.131, or 1.132. There is no other evidence entered by the Examiner and relied on by appellant.

APPENDIX C: RELATED PROCEEDINGS APPENDIX

There are no judicial or other proceedings known to the current assignee or the undersigned for appellant which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this appeal. It is firmly believed that no such proceedings exist.